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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/561,756

12/21/2005

Richard E Musty

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EXAMINER

CLAYTOR, DEIRDRE RENEE

ART UNIT

PAPER NUMBER

1627

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PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/561,756	<b>Applicant(s)</b> MUSTY ET AL.	
	<b>Examiner</b> Renee Claytor	<b>Art Unit</b> 1627	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 01 March 2011.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 14, 18, 19 and 25-28 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 14, 18, 19 and 25-28 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)            | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>3/1/2011</u> .  | 6) <input type="checkbox"/> Other: _____                          |

## **DETAILED ACTION**

### ***Response to Arguments***

Applicants present arguments over the 35 USC 103 rejections over Brooke et al. in view of Travis and Turner. Applicants argue that cannabichromene (CBC) is not abundant in most mature cannabis plants. It is argued that a sampling of the cannabinoid composition during the life cycle of several cannabis plants reveals that the proportion of CBC in the total cannabinoid fraction decreases with ageing of the plant.

Regarding the argument that several cannabis plants reveal that a proportion of CBC in the total cannabinoid fraction decreases with ageing of the plant, it is noted that Applicants have previously provided articles by Vogelmann et al., and WO 2009/125198 to prove the point that CBC is found in small amounts in mature plants. However, as pointed out previously in the Harvey et al. article, CBC has been reported as the second most abundant cannabinoid. While it is understood that CBC decreases in certain types of mature plant types, this is not the case in all plant types as evidenced by Harvey. Therefore, the above argument is not found persuasive.

Applicants further argue that Brooke et al. makes no comment on the activity of each of the specified ingredients of cannabis and one would not obtain any suggestion from Brooke to use CBC for treating any particular disorder. It is argued that there are dozens of cannabinoids known in cannabis. It is also argued that there is no reason to combine Travis and Turner with Brooke to lead to the present invention.

In response to the above arguments, it is noted that Brooke et al. teaches that the active ingredients of cannabis are four components including THC, CBN, CBD and

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CBC. Therefore, Brooke et al. limits the cannabinoid components to four and not all of the potential cannabinoids in a plant. Further, Brooke specifically points to the medicinal use of cannabis which would indicate that these four components are involved in the medicinal uses listed. From this statement it is clear that CBC contributes to the medicinal effects of which include stress and depression. It would be obvious to a person of ordinary skill in the art to combine the teachings of Travis which teaches pharmaceutical compositions comprised of CBC that are in a pharmaceutically carrier and routes of administration that overlap with those claimed. Further, it would be obvious to combine Turner with Brooke and Travis as Turner teaches that CBC is one of the most abundant naturally occurring cannabinoids. Travis was not used for the teaching of any other treatment method but solely for the teaching that CBC can be in a pharmaceutical composition.

Applicants argue that at the time that the instant invention was filed, there was evidence in the art which suggested that cannabis was responsible for mental health problems such as depression and have provided two articles (Henry and Rey) to back up this point.

In response to the above arguments, it is noted that the Henry article discusses that there is a fourfold increase in major depression associated with cannabis use. The Rey article concludes from their study that an association was found between depression and cannabis use; however, there is no clarification of what comes first or whether both problems are the result of common aetiological factors. Therefore, it cannot be determined that cannabis causes depression from either reference. An

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article provided by Chen et al. (Soc. Psychiatry Psychiatr Epidemiol (2002) 37: 199-206) shows that the main finding of their study is that marijuana use and marijuana dependence signal no more than moderately increases risk of major depression. The authors make the conclusion that there is not a strong causal influence with respect to occurrence of major depression and marijuana use (see Discussion). Therefore, there is discrepancy within the art concerning the link between depression and marijuana use at best and the argument that one of skill in the art would have been prejudiced against selecting CBC to use as a medicine to treat mood disorders is not persuasive. If there is a teaching in the art that cannabinoids may treat depression and there is discrepancy in the art that marijuana use causes depression, it would be reasonable for one of skill in the art to try to treat depression with marijuana per the teachings of Brook et al.

Applicants present arguments over the 35 USC 103 rejection over Whittle et al. in view of Turner et al. Applicants present some of the same arguments regarding the amount of CBC in mature plants as above and those arguments have been addressed. Applicants further argue that Whittle does not link any specific cannabinoid to treat depression and does not link the use of CBC to treat depression.

In response to the above arguments, it is noted that Whittle teaches therapeutic extracts of cannabis, which includes CBC (paragraph 0052). Therefore, Whittle does teach that one of the therapeutic substances of the invention includes CBC and that the extracts taught are useful in the methods of treating depression (paragraph 0056).

Regarding the Double Patenting rejection, Applicant's assert that because the present claims recite CBC and the claims of co-pending application 11/760,364 recite

CBG, the two inventions are not obvious because they use two different compounds.

This argument is not found persuasive because as stated in the rejection, both application teach methods of treating a mood disorder with a naturally occurring cannabinoid. During the interview on February 16, 2011, Applicants discussed submitting information to explain the difference between CBC and CBG.

Please see the rejections given below for Applicants convenience.

### ***Claim Rejections – 35 U.S.C. § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 14, 18-19, 25-28 rejected under 35 U.S.C. 103(a) as being unpatentable over Brooke et al. (US Patent 6,328,992) in view of Travis (US Patent 6,541,51) and Turner et al. (J Clin Pharmacol 1981; 21: 283S-291S).

Brooke et al. teach that medicinal uses, such as depression, have been found for the active ingredients of cannabis, including cannabichromenes (meeting the limitation of claim 14; Col. 1, lines 23-33).

Brooke et al. does not teach that the cannabichromene compound is an extract of a cannabis plant that contains greater than or equal to 30% CBC or the route of administration.

Travis teaches pharmaceutical compositions comprised of cannabichromene compounds. Travis further teaches that the composition includes a suitable carrier and routes of administration that encompass claims 19 and 28 (paragraph 0106).

Turner et al. teach that cannabichromene is a crude drug made from cannabis plants and is one of the most abundant naturally occurring cannabinoids (meeting the limitations of claims 18 and 25-27; see Introduction). Turner et al. further teach that THC and CBC are the major cannabinoids in freshly harvested drug-type cannabis material (see page 285S, first full paragraph).

Accordingly, it would have been obvious to a person of ordinary skill in the art at the time of the invention, to treat mood disorders such as depression with cannabichromene compounds because of the teachings of Brooke et al. that cannabichromenes are useful in treating such disorders as depression. It would have further been obvious to use the cannabichromene composition taught by Travis and Turner et al. to treat depression, because Travis and Turner et al. teach cannabichromene compositions that are useful as pharmaceutical compositions. One would have been motivated to use the cannabichromene compositions taught by Travis and Turner et al. to treat depression with a reasonable expectation of success because Brooke et al. teaches that cannabichromenes show medicinal use in treating depression. It would further be obvious that the CBC amount would be higher because of the teachings of Turner that CBC is the major cannabinoid in freshly harvested drug-type cannabis material, which would make the amount of 30% obvious.

Claims 14, 18-19, 25-28 rejected under 35 U.S.C. 103(a) as being unpatentable over Whittle and al. (US Pg/Pub 2005/0042172) in view of Turner et al. (J Clin Pharmacol 1981; 21: 283S-291S).

Whittle et al. teaches therapeutic compositions that are inhaled as a vapour (paragraph 0030) that comprise one or more natural or synthetic cannabinoids, which includes cannabichromene (paragraphs 0049 and 0051). It is further taught that the compositions that contain natural cannabinoids which are derived from cannabis plants (paragraphs 0042, 0043 0053). The compositions are taught to comprise carriers or solvents (paragraph 0072). The compositions are used in methods of treating inflammatory pain particularly that associated with depression (paragraph 0056), in which it is considered that the composition would necessarily be treating depression.

Whittle et al. does not teach that the CBC extract from the cannabis plant contains greater than or equal to 30% CBC of the total cannabinoid content.

Turner et al. teach that cannabichromene is a crude drug made from cannabis plants and is one of the most abundant naturally occurring cannabinoids (meeting the limitations of claims 18 and 25-27; see Introduction). Turner et al. further teach that THC and CBC are the major cannabinoids in freshly harvested drug-type cannabis material (see page 285S, first full paragraph).

Accordingly, it would have been obvious to a person of ordinary skill in the art at the time of the invention, to treat mood disorders such as depression with cannabichromene compounds because of the teachings of Whittle et al. that cannabichromenes are useful in treating such disorders as pain associated with



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depression. One would have been motivated to use cannabichromene to treat depression with a reasonable expectation of success because Whittle et al. teaches that cannabichromenes show medicinal use in treating pain associated with depression, which would necessarily treat depression. Further, Turner teaches that CBC is one of the most abundant naturally occurring cannabinoids; therefore, it would be obvious that the content of CBC would be higher to treat a mood disorder.

### ***Double Patenting***

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the “right to exclude” granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 14, 18-19, 25-28 provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 3, 5, 12, 14 of copending Application No. 11/760,364. Although the conflicting claims are not identical,

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they are not patentably distinct from each other because both applications teach methods of treating a mood disorder with a naturally occurring cannabinoid.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

### ***Conclusion***

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

### ***Contact Information***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Renee Claytor whose telephone number is (571)272-8394. The examiner can normally be reached on M-F 8:00-4:30.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan can be reached on 571-272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Renee Claytor

/SREENI PADMANABHAN/  
Supervisory Patent Examiner, Art Unit 1627